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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,681	03/15/2004	Hirokazu Annoura	001560-454	8653

21839 7590 01/17/2006

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EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/799,681

Applicant(s)

ANNOURA ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11,12,14-16 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-12,14-16 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/14/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1625

### DETAILED ACTION

Claims 11-12, 14-16, , 19-21 are pending.

Claim 21 is newly added method of treating claim.

Claim 20 is drawn to a compound of formula II.

Applicants have elected group II drawn to compounds and pharmaceutical compositions , wherein X is an OH, E is an O, B is an alkylene, A is a connecting bond.

Applicants request to rejoin Group I and III has been considered , however the request has been denied. As explained in the previous action the core is not novel and the search is burdensome to the PTO. The groups are patentably independent and distinct.

See US 6706734 wherein E is a connecting bond and X is an OH. This reads on Group I of the restriction.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

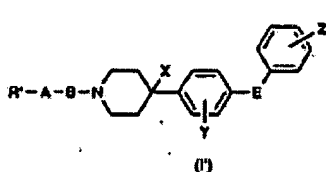
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1625

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6838470 and claims 1-10 of US 6455549. Although the conflicting claims are not identical, they are not patentably distinct from each other because they read on the compounds and pharmaceutical compounds of the invention.

Applicants compounds are drawn to a formula as given below:-



wherein E is an O, X is an OH, A is a bond, B is a substituted alkylene chain and R1 is a phenyl, benzoyl or a phenoxy group.

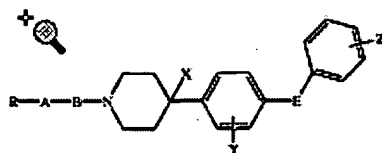
Determination of the scope and content of the prior art (MPEP §2141.01)

The US 6838470 and 6455549 both teach the compounds and pharmaceutical compositions of the instant invention.

US 6455549 teaches the compositions of the following formula wherein X can be a Hydroxy, B is an alkylene chain, A is a bond and R is a phenyl, benzoyl or phenoxy.

Art Unit: 1625

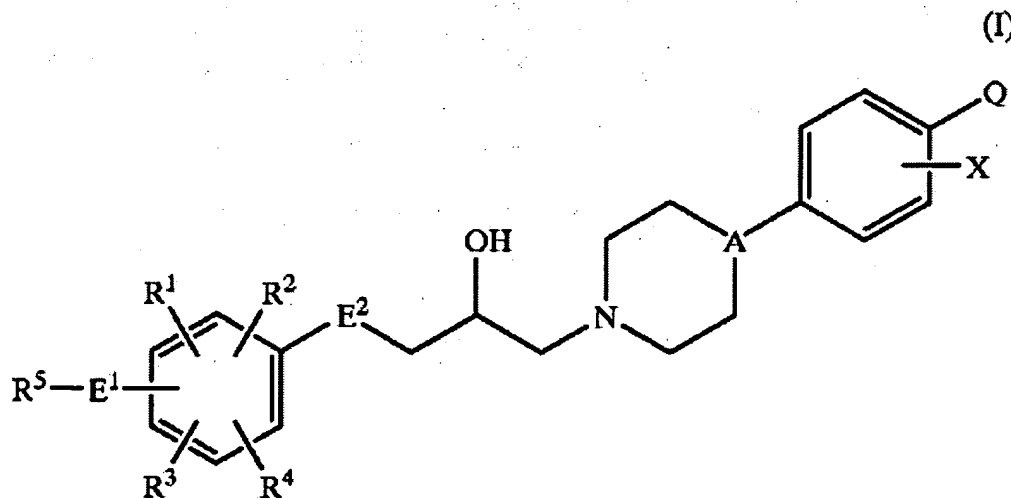
1. A pharmaceutical composition for the alleviation or treatment of symptoms due to ischemic diseases or symptoms derived from migraine containing, as an effective ingredient, a compound having the formula (I) or its pharmaceutically acceptable salt:



wherein, R is a hydrogen atom, an optionally substituted phenyl group, an optionally substituted phenoxy group, or an optionally substituted benzoyl group, A is a connecting bond, a cycloalkylene group, or an alkenylene group optionally substituted with a lower alkyl group, B is an alkylene group optionally substituted with a hydroxyl group or an alkoxy group or a group  $\text{—NHCO(CH}_2\text{)}_n\text{—}$ , where n is an integer of 1 to 5, E is a connecting bond, an oxygen atom, or a methylene group, X is a hydroxyl group or a hydrogen atom, provided that, when E is an oxygen atom or a methylene group, X is not a hydrogen atom, and Y and Z may be the same or different from each other and represent a hydrogen atom, a halogen atom, an alkoxy group, or an alkyl group optionally substituted with a halogen atom; and

US 6838470 teaches compounds and compositions of the same scope when A is a  $\text{—C(OH)—}$ .

1. A compound having the formula (I) or its salt, hydrate, or hydrate salt:



wherein R<sup>1</sup> to R<sup>4</sup> each independently represent a hydrogen

Art Unit: 1625

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Thus since the genus is clearly disclosed one of skill in the art would have found it obvious to make the modification to obtain the compounds of the invention.

***Conclusion***

Claims 11-12, 14-16, and 19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
January 11, 2006

*R. Desai*  
1/11/06